Title: EARLY LOW DOSE EVEROLIMUS HYBRID STRATEGY IS SAFE AND EFFECTIVE IN HEART TRANSPLANT PATIENTS WITH REDUCED POST OPERATIVE RENAL FUNCTION

Category: Heart Failure and Cardiomyopathies

Abstract

INTRODUCTION : Many Heart Transplantation Recipients have a significant persistent Post operative reduced renal function which poses a Challenge and Dilemma for the Transplant Team in terms of type , dose and Timing of immunosuppression to be continued. Everolimus has been studied as an alternative to Tacrolimus for immunosuppression. We studied 12 POST Heart Transplant patients with Persistent Post Transplantation Azotemia who were started on a combination of Everolimus and Tacrolimus from the First week after Heart Transplantation.

METHODS : We studied 12 Patients aged between 48- 69 years of age (10 males and 2 females). The Mean ischeamic time was 190 minutes (range 166-250 mins) . Preoperative Creatinine was 1.5 mg /dl (range 0,8-2.0 mg/dl) . All received Induction Therapy with Basiliximab 20 mg in two doses one before surgery and another on the Fourth day . Since above cases had a Post operative creatinine in the range of 2.2-2.5 mg/dl on the fifth day post Transplant , all were started in Everolimus 0.25 mg bid initially with low dose Tacrolimus started once the serum Creatinine fell below 1.5 mg/dl (group B). Target Tacrolimus serum level was assigned at 3-5 ng/dl. All patients received Mycophenolate 360 mg bid and prednisolone 10 mg . All patients were followed up for a period of 12 months .

The Other patients with Normal post operative creatinine levels were given Standard doses of Tacrolimus (group A) . Total leukocyte count (TLC) was equivalent in Both the groups at the end of the First week

Statistical analysis of comparision of Creatinine values at 12 months between group A on Standard doses of Tacrolimus (15 patients) and Group B on everolimus and low dose tacrolimus (group B) was done using the Mann Whitney " U "' test.

RESULTS : Only 1 out 12 patients had a Creatinine Rise a week after starting above combination .

At the end of the observation period (12 months) Serum creatinine range was 0.8 to 1.5 mg /dl (mean 1.04 mg/dl) for Group A (tacrolimus) and 0.7 to 1.5 mg/dl (mean 0.85 mg/dl) for group B (Everolimus) . The difference in creatinine levels between the two groups was Non Significant by the Mann whitney "U " test . No patient required stoppage of Tacrolimus in the observed period . One patient had Herpes Zoster 2 months after Surgery which resolved with Anti Viral drug. No other Infection was noticed. In all patients sternal and skinn Wound healing WAS Normal . No patient had New Pleural or pericardial effusion .

CONCLUSION : We conclude that early introduction of Everolimus at 0.25 mg bid is a safe strategy to avoid progressive renal dysfunction in Post Heart Transplant patients with Persistent Azotemia (creatinine levels above 2 mg/dl) . No adverse effects like poor wound healing or pleural effusions were Noticed in our Small study cohort .

MANN WHITNEY U TEST COMPARISION BETWEEN TACROLIMUS AND EVEROLIMUS GROUPS AT 6 MONTHS POST HEART TRANSPLANT.